## CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-634/S-008, S-009 20-635/S-007, S-008

## **CHEMISTRY REVIEW(S)**

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SUPPLEMENTAL NDA CHEMIST'S REVIEW NAME AND ADDRESS OF APPLICANT (City and State)		1. OR	GANIZATION HFD-590	2. NDA NUMBER 20-635			
			4. AF NUMBER				
The R. W. Johnson Pharmaceutical Resear							
Route 202, P.O. Box 300 Raritan, NJ 08869-0602			5. SUPPLEMENT(S):				
			NUMBER(S)	DATE(S)			
			SE1-007	March 31, 1999			
6. NAME OF DRUG  Levaquin® Tablets			7. NONPROPRIETARY NAME Levofloxacin				
8. SUPPLEMENT(S) PROVIDES FOR:  New indication: penicillin-  resistant strains of S. pneumoniae			9. AMENDMENTS/REPORTS				
10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSE	)	12. RELATED IND/NDA/DMF(S) IND 36,627, 38,368 NDA 20-634				
Antibacterial	[X] Rx [ ]OT	C					
13. DOSAGE FORM(S)	14.	POTENCY	(IES)				
Injection			/mL, 5 mg/mL				
H <sub>3</sub> C	СН3						
17. COMMENTS: This supplement supports a re S. pneumoniae to specifically indicate that Levaquin S. pneumoniae. There are no changes to the Descriptionsert. A claim of categorical exclusion from Envir There is no information to indicate that additional exclusions.	n is effective in treating per ption, Preparation for Adm onmental Assessment unde	icillin- inistration or r 21 CFR 2	resistant or How Supplied sec	strains of tions of the package			
18. CONCLUSIONS AND RECOMMENDATION	ONS: From a CMC viewpo	int, this sup	plement may be app	proved.			
19. REVIEWER:		int, this sup					
19. REVIEWER: NAME SIGN	ONS: From a CMC viewpo	int, this sup	plement may be app				
19. REVIEWER:		int, this sup		TED			
19. REVIEWER:  NAME  Gene W. Holbert, Ph.D.  CONCURRENCE:		int, this sup	DATE COMPLE	TED			
19. REVIEWER:  NAME  Gene W. Holbert, Ph.D.	ATURE /		9-24/9	TED			

SUPPLEMENTAL NDA						2. NDA NUMBER		
CHEMIST'S REVIEW			HFD-590	DED.	20-634			
NAME AND ADDRESS OF APPLICANT (C	ity and State	" <b>%</b>		4. AF NUM	BFK			
NAME AND ADDRESS OF APPLICANT (City and State) The R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300  Position NI 08860 0602					5. SUPPLEMENT(S):			
Route 202, P.O. Box 300	1 da		Sh.	NUMBER		DATE(S)		
Raritan, NJ 08869-0602			40	SE1-008		March 31, 1999		
				321-000	•	1VIAICH 31, 1999		
6. NAME OF DRUG			7. NO	NPROPRIET/	ARY N	AME		
Levaquin® Tablets				Levofloxacin				
•								
						<u>.</u>		
8. SUPPLEMENT(S) PROVIDES FOR:	_			9. AMENDMENTS/REPORTS				
New indication: penicillin-	esistant stra	ins of <i>S. pneu</i>	moniae					
				1				
10. PHARMACOLOGICAL CATEGORY	11 HOV	V DISPENSE	<u> </u>	12 DELATED INDADA (DME/S)				
IU. PHARMACULUGICAL CATEGORT	11. HOV	V DISPENSE	ָּע	12. RELATED IND/NDA/DMF(S) IND 36,627, 38,368				
Antibacterial		[X] Rx [ ]O]	rc .	NDA 20-635				
/ Bittobetti la	1	[,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		1120 033				
13. DOSAGE FORM(S)	<u> </u>	14.	POTENCY	(IES)				
Tablets			250 and	d 500 mg				
						<del></del>		
15. CHEMICAL NAME AND STRUCTURE				16. MEMOI	RAND.	A		
S-(-)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-			xo-7 <i>H</i> -					
pyrido[1,2,3-de][1,4]benzoxazine-6-carbox	ync acid ne	minyurate						
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17. COMMENTS: This supplement supports a rev	ision to the	sponsor's app	roved comm	•	-			
S. pneumoniae to specifically indicate that Levaquin						ains of S. pneumoniae.		
There are no changes to the Description or How Supplied sections of the package insert. A claim of categorical exclusion from								
Environmental Assessment under 21 CFR 25.31(b) is contained in the cover letter. There is no information to indicate that additional environmental information is required.								
on a commentar anormation is required.								
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18. CONCLUSIONS AND RECOMMENDATIONS: From a CMC viewpoint, this supplement may be approved.								
		•			FF. •			
19. REVIEWER:								
	ATURE	<u> </u>		DATE COM	PLET	ED		
Gene W. Holbert, Ph.D.	. !	<b>SI</b>		Sept	23,	1499		
Norman R. Schmuff, Ph.D.								
STRIBUTION: X Original: NDA 20-634	X	HFD-590: N	Schmuff	Х	HFD-	590: RAnderson		
X Division File: HFD-59	90 X	HFD-590: C	Holbert	X		830: CChen		